JAN 0 7 2002

Name of Company: Limerick Inc.
Premarket Notification – 510(k)
Name of Devise: The pj•s*comfort*® Portable Electric Breast Pump

EXHIBIT #1
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510(K) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K012275

1. **Submitter's Identification:**

   Limerick Inc.
   903 North San Fernando Blvd., Suite 5
   Burbank, California 91504

   Date Summary Prepared: March 27, 2001

2. **Name of the Device:**

   pj•s *comfort*® Portable Electric Breast Pump

3. **Predicate Devices Information:**

   K#850705, White River Portable Electric Breast Pump, White Rive, Division of Natural Technologies, Inc.

   K971543, Luxmatic 12-15 ISC Portable electric Breast Pump, KaWeCo GmbH

4. **Device Description:**

pj•s *comfort*® Portable Electric Breast Pump (suction device with a compressor unit) contains a diaphragm-type pump with a vacuum regulator (between 150mm Hg and 220mm Hg) which includes a filter, soft silicone tube and plastic tubing. An accessory kit includes silicone breast cups and a collection cup. The device is battery and line-powered for 12V DC by an external transformer or utilizes a 12V-battery pack. The device is controlled by an electric sensor with intermittent suction at approximately 30-45 cycles. The bacterial filter contains an optical sensor, with an automatic shut off. The motor stops when liquid is sucked into the bacterial. The pump can be used with the Single Breast Pump Kit #6166-3 or the Double Breast Pump Kit #6166-0. Dimensions are 7 x 12 x 3 .5 inches and the weight is 4.5 lbs.

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Suction is controlled by the pump automatically. It will automatically be released when the adjusted vacuum is reached. An electronic sensor is built-in for automatic motor shut off: If milk flows into the bacterial filter, the motor stops automatically at once and the inside valves from the pump cannot be damaged through the milk. The bacterial filter should be changed regularly.

5. **Intended Use:**

The intended use of the electrically powered (diaphragm-type) suction device is to express milk from the breast.

6. **Comparison to Predicate Devices:**

Table of Comparison to Legally Marketed Device:

The following is a comparison chart outlining differences and similarities between **pj•s** *comfort*® Portable Electric Breast Pump, White River Portable Electric Breast Pump and Luxmatic 12-15 ISC Portable Electric Breast Pump:

PARAMETER	pj's *comfort*	WHITE RIVER (K#850705)	LUXMATIC (K#971543)
Pump Type	Diaphragm	Same	Same
Vacuum Control Cycle	Yes	Same	Same
Adjustable Suction Range	150-220 mm Hg	Not available	Same
Vacuum Gauge	Yes	Same	Same
Bacteria Filter	Yes	Not available	Same
Collection Bottles	Yes	Same	Same
Single Patient Use	Yes	Same	Same
Indications For Use	Same	Same	Same
Timer	Yes	Not available	Not available
Weight	4.5 lbs.	10 lbs.	4.5 lbs.

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7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

a) Testing information demonstrating safety and effectiveness of the **pj•s** *comfort*® Portable Electric Breast Pump in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlined Electrical, Mechanical and Environmental Performance Requirements.

b) Patient-contacting material includes both skin contacted material (breast cups) and milk contacting materials. 21 CFR Parts 176, 177 and 178 were reviewed in order to ascertain materials approved for food contact. Materials are approved for food contact.

8. Discussion of Clinical Tests Performed:

Non-Applicable

9. Conclusions:

The **pj•s** *comfort*® Portable Electric Breast Pump has the same intended use, similar design and technology as the White River Portable Electric Breast Pump and the Luxmatic 12-15 ISC Portable Electric Breast Pump. As our comparison chart indicates, as well as our testing data, the **pj•s** *comfort*® Portable Electric Breast Pump raises no new questions of safety or effectiveness. Thus, when compared to the predicated device, the **pj•s** *comfort*® Portable Electric Breast Pump does not incorporate any significant changes in intended use, method or operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2002

Ms. Patricia A. Kelly
President
Limerick, Inc.
903 N. San Fernando Boulevard
Suite 5
BURBANK CA 91504-4327

Re: K012275
Trade/Device Name: pj•s comfort® Portable Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: November 9, 2001
Received: November 13, 2001

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Name of Company: Limerick Inc.
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EXHIBIT B

INDICATIONS FOR USE

510(K) Number: K012275

Device Name: The pj•s*comfort*® Portable Electric Breast Pump

Indication for Use: The intended use of the electrically powered (diaphragm-type) suction device is to express milk from the breast of lactating women.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **or** **Over-the-Counter Use** ___x___
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012275